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**APPLICATION FOR PATENT TERM ADJUSTMENT 37 C.F.R. § 1.705(b)**

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| Applicants     | : | Dobie et al.   |
| App. No.       | : | 10/789,526   |
| Filed          | : | February 26, 2004  |
| For            | : | MODULATION OF GROWTH HORMONE RECEPTOR<br>EXPRESSION AND INSULIN-LIKE GROWTH FACTOR<br>EXPRESSION |
| Examiner       | : | Epps-Smith, Janet L.   |
| Group Art Unit | : | 1633   |
| Conf #         | : | 9932   |

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**Mail Stop Petition**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

After review of the file history and Image File Wrapper (IFW), Applicants hereby submit this Application for Patent Term Adjustment (PTA) to correct the Office's PTA calculation of 53 days. A Notice of Allowance was mailed in the above-referenced application on November 17, 2009, and the issue fee is being paid as of the date of this petition. Therefore, this application under 37 C.F.R. § 1.705(b) is timely filed no later than the payment of the issue fee and no earlier than the date of mailing of the Notice of Allowance.

Applicants submit that the PTA sent with the Notice of Allowance, 53 days, is inconsistent with the calculation listed on PAIR, which lists a PTA of 24 days. In addition to this error, Applicants submit that they are entitled to a longer period of patent adjustment under 35 U.S.C. § 154(b) in light of the decision in *Wyeth v. Dudas*, No. 2009-1120 (Fed. Cir. Jan. 7, 2010), and request that the Office recalculate Applicants' PTA upon issuance in accordance with that ruling.

Applicants believe the available PTA to be **235 days** based on the following facts:

1. Applicants believe they are entitled to **161 days** of PTA under **35 U.S.C. § 154(b)(1)(A)**. This provision provides a one-day extension of patent term for every day that issuance of a patent is delayed due to enumerated prosecution delays by the Office (hereinafter, "prosecution delays"). Applicants' PTA calculation under 35

U.S.C. § 154(b)(1)(A) is represented in the table below, and is consistent with the calculation listed on PAIR.

2. The Office's PTA determination, dated November 17, 2009, does not account for the days of PTA under 35 U.S.C. § 154(b)(1)(B), however. Applicants submit that, in light of *Wyeth v. Dudas*, they are entitled to an additional **212 days** of PTA under 35 U.S.C. § 154(b)(1)(B), for the Office's failure to issue a patent within three years of its application filing date. Section 154(b)(1)(B) provides a one-day extension for every day greater than three years after the application filing date that it takes for a patent to issue ("issuance delay"), subject to some limitations. One such limitation is the filing of an RCE, because the § 154(b)(1)(B) patent term adjustment calculation does not include any time consumed by continued examination of the application requested by the applicant. 35 U.S.C. § 154(b)(1)(B)(i). Thus, the applicable time period to determine Applicants' § 154(b)(1)(B) PTA is the day after the date that is three years after Applicants' application filing date, February 27, 2007, to the date Applicants filed an RCE, September 27, 2007.
3. The § 154(b)(1)(B) PTA period, February 27, 2007 to September 27, 2007, encompasses 212 days. Under *Wyeth*, this 212-day delay should be reduced by any overlapping "prosecution delay" days that also occurred in this period. The Office's 160-day delay in issuing a Restriction Requirement after the application filing date occurred *before* February 27, 2007, the start of the § 154(b)(1)(B) PTA "issuance delay" period, and thus is not overlapping. However, the one day of PTO delay in failing to respond to Applicants' submission under 37 C.F.R. 1.111 filed on February 27, 2007 within four months occurred on June 28, 2007 when the PTO issued a final rejection. Therefore, there is one "overlapping day." Thus, Applicants submit they are entitled to 211 days of "issuance delay" under § 154(b)(1)(B).
4. Under *Wyeth*, the proper patent term adjustment is the sum of non-overlapping "prosecution delays" and "issuance delays," minus any Applicant delay. Thus, Applicants submit they are entitled to the sum of 161 days of "prosecution delay" and 211 days of "issuance delay," minus 137 days of Applicant delay, for a **total patent term adjustment of 235 days**.
5. Applicants may be entitled to additional "prosecution delay" PTA if the Office fails to issue a patent not later than 4 months after the date on which the issue fee is paid. Applicants therefore reserve the right to petition for additional PTA should the patent issue more than 4 months after payment of the issue fee. However, in full compliance with the requirement to petition for patent term adjustment at the earliest possible opportunity, Applicants submit this Application for Patent Term Adjustment no later than the payment of the issue fee and no earlier than the date of mailing of the Notice of Allowance.
6. Based on the OG notice dated September 10, 2009, Applicants are aware that the PTO does not calculate and inform the applicant of the patent term adjustment based upon the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B) in the notice of

allowance because it is the view of the PTO that it must know the date the patent will issue to be able to calculate the patent term adjustment based upon this provision. Therefore, the PTO has stated that "a request for reconsideration of the patent term adjustment calculation based on the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B) will be considered timely under 37 CFR 1.705(d) if filed within two months of the date the patent issued."

7. If the PTO views the above request for recalculation of PTA under the provision of 35 U.S.C. § 154(b)(1)(B) as premature because the PTO must know the date the patent will issue, Applicants reserve the right to raise the issue under 37 C.F.R. 1.705(d) within two months of the date the patent issues, relying on the above statement in the September 10, 2009 OG notice that such a request will be considered timely.

Applicants' PTA calculation is as follows:

| Actions Under 35 U.S.C. §§ 154(b)(1)(A) and (2)(C)      |   | Delays          |     |      |
|---|---|-----------------|-----|------|
| Initial   | Responsive  | PTO             | App | Over |
| 2/26/2004<br>Filing Date                                | 10/3/2005<br>Restriction Requirement                    | 160             |     |      |
| 4/13/2004<br>Notice to File Missing Parts               | 8/4/2004<br>Applicant Response                          |                 | 22  |      |
| 10/3/2005<br>Restriction Requirement                    | 3/28/2006<br>Applicant Response                         |                 | 84  |      |
| 6/13/2006<br>Non-final Action                           | 9/15/2006<br>Applicant Response                         |                 | 2   |      |
| 2/27/2007<br>Applicant Response                         | 6/28/2007<br>Final Rejection                            | 1               |     | 1    |
| 6/29/2009<br>Non-final Action                           | 10/28/2009<br>Applicant Response                        |                 | 29  |      |
| Actions Under 35 U.S.C. § 154(b)(1)(B)                  |   | PTO             | App | Over |
| 2/27/2007<br>Day after 3 Years from Filing Date         | 9/27/2007<br>Request for Continued<br>Examination (RCE) | 212             |     |      |
| Actions Under 35 U.S.C. §§ 154(b)(1)(A), (B) and (2)(C) |   | Delay & Overlap |     |      |
| Totals  | PTO Delays  | 373             |     |      |
|   | Applicant Delays  |                 | 137 |      |
|   | Period of Overlap                                       |                 |     | 1    |
|   | Patent Term Adjustment                                  | 235             |     |      |

The present application is not subject to a terminal disclaimer.

Applicants hereby request that the Office correct the calculation of PTA to reflect 235 days.

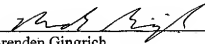
The \$200 fee prescribed by 37 CFR 1.18(e) is enclosed.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 2/17/10

By:   
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